











Structured Product Labeling (SPL) OTC Sub-team Teleconference
September 12, 2011, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Amy Deuchler, Medline Industries, Inc.
-  Susan Dunitz, Estee
-  Maureen Kapustynski, Cadbury
-  Diane O'Grady, Purdue Pharma
-  Janet Riffitts, McNeil Consumer Healthcare
-  Carl Strotz, Pfizer Consumer Healthcare
-  Lynn Walks, i4i
-  Carey Wilson, Intagras
-  Robert Wirt, Allergan
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: **October 10, 2011, 1:00pm ET (unless cancelled).**
Standing calls for 2011 will be held on the second Monday of each month only and will be cancelled as appropriate.

- Please submit any agenda topics and questions topics to Paula Markert (sub-team leader) and/or Marcia Howard at your convenience. Teleconferences will be held once there are a sufficient number of discussion topics.
- If you have a specific issue or concern and need immediate assistance, please contact Marcia directly.

III. Discussion

A. Indexing of OTC Drug SPL Files

- Indexing of indications for OTC drug products (manufactured under final monographs only) is currently being considered. At this time, if indexing were to occur, it would follow the same procedure used for prescription drug products.
- If indexing for OTC products moves forward, a meeting between industry and FDA will be requested for further dialogue on the issue.
- FDA issued a 2008 guidance on indexing that might be useful background information. The guidance can be accessed at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072317.pdf>.

B. SPL Forms

1. Current status of the new form; is it still being beta tested?
2. Can it be used now and will it be further revised?
3. Will new form automatically assign UNIIs?

The forms are still being tested but can be used at this time. UNIIs are not automatically assigned but with the new version of the X-forms, when you begin typing the name of an ingredient that has already been made public, a list of ingredients will appear for your selection.

If anyone has used the new X-forms and would be willing to share his/her experience, please let Marcia Howard (CHPA staff) know.

C. ER/DL Sub-team call with Dun & Bradstreet Representatives

- Representatives from Dun & Bradstreet (D&B) will be participating on the next ER/DL sub-team calls scheduled for September 14th and 28th at 1:00 pm ET. Please contact the leaders of this sub-team (see contact info below) to participate.
- To maximize the number of companies able to participate, please use only one conference call line per company.

IV. SPL Educational Forums/Information (*For Your Information*)

- A. **FDA Training Sessions:** Please visit the Data Standards Council website for details about upcoming agency training opportunities.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 240184

Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.

SPL Working Group Wikipage: <http://spl-working-group.wikispaces.com/Drug+Listing> (no log-on or password needed).

- C. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover (COWALL-HANOVER.PATRICIA.L@LILLY.COM) or Jessica Dunn Skorupski if you want to get the email information (JSkorups@its.jnj.com).

- D. **SPL Generics Sub-team calls:** Not currently holding regular calls. Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

- E. **Medical Products Sub-team calls:** Every other Thursday at 10:30 am EST Please email Sub-team leader Myron Finseth (myron.finseth@medtronic.com) if you want to join this sub-team.

Telephone Number: 770-657-9270
Participant passcode: 745896

- F. **SPL Usage Discussion Group**
Please email or call Terry Brunone (Theresa.M.Brunone@gsk.com; +1-215-751-3210) or Gary Saner (gsaner@reedtech.com; +1-610-731-7192) if you wish to join the discussion group.

- G. **Homeopathic Sub-team** (*additional sub-team; not replacing SPL OTC sub-team*)

Contact sub-team leader Travis Borchardt (tborchardt@enzy.com) if you wish to join this sub-team.

MDH/09-14-11

SPL OTC Sub-team 12 September 2011 091411.doc
Last Revised: September 14, 2011 Sent: September 14, 2011